Remarks

Claims 29-32 are pending in the subject application. Claims 30-32 have been cancelled, without prejudice, as being redundant in view of the amendments to claim 29. Applicants reserve the right to pursue subject matter affected by these amendments in later filed or co-pending continuation/divisional applications. Upon entry of the foregoing amendments, claim 29 will be before the Examiner for consideration.

Claims 29-32 stand rejected under 35 USC § 112, first paragraph. Applicants assert that the amendments to the claims, and the Second Gauldie Declaration provided herewith, obviate this rejection. Applicants' appreciate the Examiner's indication at pages 2-3 of the office action that the methods as claimed are "enabling for a method of providing a protective immune response against HSV-2 infection." The claims have been amended to recite that the antigen expressed by the andenoviral vector is derived from HSV-2, and that the pathogen being treated or prevented is HSV-2. This amendment addresses the Examiner's concern at page 9 of the office action that the "claims require no relationship between the antigen of the adenoviral vector and the disease or disorder to be treated or prevented." Thus, in light of these amendments, Applicants request reconsideration of the 35 USC § 112, first paragraph, rejection.

Applicants thank the Examiner for the courtesy extended during the October 20, 2003 telephonic interview. During the interview the primary issue discussed was enablement of the methods as claimed. It is Applicants understanding that the Examiner's primary concern is that the demonstration of protection against HSV-2 in mice enables protection against all pathologic conditions in all animals. As discussed below, Applicants believe that the amendments to the claims address all of the Examiner's concerns. It must be noted that the Applicants believe that the methods are enabled for diseases or disorders other than HSV-2 and intend to pursue claims to other conditions in other applications. The claims in the present application have been amended to expedite prosecution and a notice of allowance. Furthermore, as discussed in more detail below, Applicants believe that the mouse data they provided in Dr. Gauldie's first declaration is correlative to protection in higher mammals. Applicants ass rt there is

a more than reasonable correlation between the mice data they have provided in Dr. Gauldie's first declaration and the reasonable expectation of protection in other animals. As further support, Applicants provided a Second Declaration of Jack Gauldie (filed September 3, 2003) which summarizes three studies that demonstrated effective immunization in mice, dogs and humans using the same adenoviral vector.

To reiterate, based on the Examiner's indication that methods for protection against HSV-2 are enabled, Applicants do not believe any enablement issues remain after the amendments to claim 29. Applicants have previously provided a declaration from Dr. Jack Gauldie which showed that treatment of mice with an adenoviral vector expressing an antigen derived from HSV-2 according to the methods as claimed confers immunity against HSV-2. Furthermore, in the Second Gauldie Declaration, Dr. Gauldie provided data summary of studies conducted in mice, dogs, and humans using the same adenoviral vector. An adenoviral vector expressing a melanoma related antigen was administered to mice and was shown to generate an immune response that involved activation of cytotoxic T-cells. The same adenoviral vector was administered to dogs and humans. An immune response similar to that observed in the treated mice was observed in both the treated dogs and humans. These studies demonstrate that an immune response generated from an antigen-expressing adenoviral vector, when observed in mice would be expected to be achieved in higher mammals without undue experimentation. In light of the studies provided by Dr. Gauldie in his second declaration, one skilled in the art would expect that the therapeutic result the inventors have shown in mice would reasonably correlate to similar protection in higher mammals as well. The courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857 (CCPA 1980); *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995); *Ex parte Maas*, 9 USPQ2d 1746 (Bd. Pat. App. & Inter. 1987); and *Cross v. Lizuka*, 753 F.2d 1040 (Fed. Cir. 1985). The generous *in vitro* and *in vivo* data Applicants have submitted in Dr. Gauldie's First and Second Declarations establishes that treatment or prevention of HSV-2 is reasonably predictive when using the methods as claimed.

Claims 29-32 stand rejected under 35 USC § 103, as being obvious over Henning in view of Wang. Applicants have previously provided extensive remarks and expert

evidence establishing why Henning and/or Wang do not come close to realizing the invention recited in claim 29. See Supplemental response filed December 4, 2003. Furthermore, Applicants assert that the amendments to claim 29 obviate this rejection. Claim 29 has been amended to recite that "said method vaccinates said recipient such that the onset of infection by HSV-2 is inhibited or prevented upon challenge to recipient by HSV-2." It cannot be said that Henning or Wang, either alone or in combination, teach all of the elements of claim 29, and more importantly, it cannot be said that they enable a vaccination method as claimed in amended claim 29. In view of these amendments, and remarks, and remarks provided in earlier filed responses, Applicants respectfully request reconsideration and withdrawal of this 35 USC § 103 rejection.

Applicants assert that all pending claims are in condition for allowance, and such action is respectfully requested. The Examiner is invited to call the undersigned if clarification is needed on any aspect of this Amendment, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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